

Message Text

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11

ORIGIN HEW-08

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DRAFTED BY DHEW/FDA:LRSHELTON

APPROVED BY SCI/SA:MSBEAUBIEN

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R 162156Z AUG 74

FM SECSTATE WASHDC

TO AMEMBASSY VIENNA

UNCLAS STATE 180665

E.O. 11652: N/A

TAGS: CASC, AU(MAHLER, MARY L.)

SUBJECT: MEDICATION FOR MARY L. MAHLER

REF: VIENNA 6913

STATE 171132

GEROVITAL AND ASLAVITAL ARE REGARDED AS NEW DRUGS AS THAT TERM IS DEFINED BY THE FEDERAL FOOD, DRUG AND COSMETIC ACT. THE ACT PROHIBITS INTERSTATE SHIPMENT OF A NEW DRUG, INCLUDING THE IMPORTATION THEREOF, WITHOUT APPROVAL OF A NEW DRUG APPLICATION EFFECTIVE WITH RESPECT TO THAT DRUG. THE ONLY EXCEPTION TO THIS RULE IS WHEN THE ARTICLE IS EXEMPT FROM THE BAN ON INTERSTATE DISTRIBUTION OF UNAPPROVED NEW DRUGS BY VIRTUE OF THE FACT THAT IT IS INTENDED SOLELY FOR INVESTIGATIONAL USE AND IS COVERED BY A NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION ON FILE WITH FDA. THERE IS NOT ON FILE WITH THE FDA AN APPROVED NEW DRUG APPLICATION PROVIDING FOR THE COMMERCIAL DISTRIBUTION OR IMPORTATION OF GEROVITAL OR ASLAVITAL. ONE FIRM, ROM-AMER PHARMACEUTICALS OF BEVERLEY HILLS, CALIFORNIA HOLDVNG NOTICE OF CLAIMED EXEMPTION FOR GEROVITAL H-3 PURSUANT TO THIS EXEMPTION THAT MAY HANDLE INTERSTATE SHIPMENT OF GEROVITAL H-3 INTENDED SOLELY FOR DISTRIBUTION TO QUALIFIED EXPERTS WHO ARE CONDUCTING CLINICAL INVESTIGATIONS TO DEEM ITS SAFETY AND

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EFFECTIVENESS. WITH THIS SINGLE EXEMPTION FDA CANNOT

APPROVE RELEASE FOR IMPORTATION OF GEROVITAL H-3 OR
ASLAVITAL. KISSINGER

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NNN

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